



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/445,805	05/22/95	CLARK	R P0943
18N2/0214			EXAMINER
JANET E HASAK GENENTECH INC 460 POINT SAN BRUNO BLVD SOUTH SAN FRANCISCO CA 94080			ART/UNIT. II. PAPER NUMBER 11 1811
DATE MAILED: 02/14/97			

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12-2-96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), - days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-17 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 18-29 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-17 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1811

15. Claims 18-29 have been cancelled. Therefore the double patenting rejection under 35 USC 101 as claiming the same invention as claims 18-29 of prior US patent No. 5,562,428 has been overcome.

16. Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to specific renal disorders (Example 1), Aids-related cachexia, head-injured patients who presented with hypercatabolism and nitrogen loss Example 2), and diabetes (Example 3). See M.P.E.P. §§ 706.03(n) and 706.03(z).

17. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-8, 10, and 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, and 9-12 of U.S. Patent No. 5,565,428. Although the conflicting claims are not identical,

Serial Number: 08/445805

-3-

Art Unit: 1811

they are not patentably distinct from each other because '428 is related to '805 as species to Genus.

18. Claims 1-5 and 7-17 would be allowable upon filing of a proper Terminal Disclaimer. Claim 6 is not enabled.

5 Any communication regarding this application should be addressed to P. Lynn Touzeau, Ph.D., whose telephone number is (703) 308-3965.

PTT

2-12-97

CTsang
CECILIA J. TSANG
SUPERVISORY PATENT EXAMINER
GROUP 1800